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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/963,365	09/27/2001	Kazuo Kondo	0425-0854P	9474

2292 7590 11/23/2001

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EXAMINER
STILLER, KARL J

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 11/23/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application No. 09/963,365	Applicant(s) KONDO ET AL.	
	Examiner Karl Stiller	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Peri d for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-7 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-7 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

This application claims benefit of foreign application Japan 2000-294802, filed 09/27/2000

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Moot as App is canceled cls. 4-7

Claims 4-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4-7 provides for the use of "the compound as defined in Claim 1 for manufacturing a medicine", but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 4-7 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

In order to expedite prosecution herein, Claims 4-7 will be treated as a method of manufacturing a medicament or a compound (see Claim 7).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(1) Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Simons et al (See also Schultz et al.)

Simons et al. teaches a method of preventing or treating atherosclerosis, which is a disease caused by oxidated low density lipoprotein (LDL) in vivo, comprising the administration of Vitamin E (α-tocopherol) (see p. 496, abstract, lines 1-21, column 1, line 1 through p. 497, column 1, line 48, p. 499, table 2, p. 500, column 1, line 11 through column 2, line 24, line 51 through p. 501,column 1, line 4).

Schultz et al. discloses that the administration of α-tocopherol necessarily results in its metabolism to 2,5,7,8-tetramethyl-2(2'-carboxyethyl)-6-hydroxychroman (see p. 1, abstract, p. 2, lines 13-21, p. 6, lines 24-30).

(2) Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Christen et al. (See also Darko et al. and Schultz et al.)

Christen et al. teaches a method of preventing or treating atherosclerosis, which is a disease caused by oxidated low density lipoprotein (LDL) in vivo, comprising the

administration of α-tocopherol and/or γ-tocopherol via diet (see p. 3217, abstract, lines 1-25).

Schultz et al. discloses that the administration of α-tocopherol necessarily results in its metabolism to 2,5,7,8-tetramethyl-2(2'-carboxyethyl)-6-hydroxychroman (see p. 1, abstract, p. 2, lines 13-21, p. 6, lines 24-30).

Darko et al. discloses that the administration of γ-tocopherol necessarily results in its metabolism to 2,7,8-trimethyl-2-(2'-carboxyethyl)-6-hydroxychroman (see p. 648, abstract, column 1, line 19 through column 2, line 10).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over HerbiesNaturals and U.S. Trademark 2169587 in view of Schultz et al., Darko et al., and Christen et al.

HerbiesNaturals discloses Gamma E+; a medicament comprising α-tocopherol, γ-tocopherol, and mixed tocotrienols having been manufactured. U.S. Trademark 2169587 discloses the date of Gamma E+ first used in commerce as June 1, 1997.

The references do not particularly disclose the use of at least one hydroxychromane compound herein (see Claim 1) in the manufacture of an anti-oxidant medicine.

It would have been obvious to modify the primary reference by employing at least one known metabolite of α-tocopherol and/or γ-tocopherol, or α-tocopherol, α-tocotrienol, γ-tocopherol, or γ-tocotrienol in the manufacture of a medicament for anti-oxidant purposes.

Schultz et al. discloses that the administration of α-tocopherol necessarily results in its metabolism to 2,5,7,8-tetramethyl-2(2'-carboxyethyl)-6-hydroxychroman (see p. 1, abstract, p. 2, lines 13-21, p. 6, lines 24-30). Darko et al. discloses that the administration of γ-tocopherol necessarily results in its metabolism to 2,7,8-trimethyl-2-(2'-carboxyethyl)-6-hydroxychroman (see p. 648, abstract, column 1, line 19 through column 2, line 10). Christen et al. discloses the necessity of γ-tocopherol in an anti-oxidant method employing α-tocopherol (see p. 3217, abstract, lines 1-25).

One of ordinary skill would be motivated to employ at least one known metabolite of α-tocopherol and/or γ-tocopherol, or α-tocopherol, α-tocotrienol, γ-tocopherol, or γ-tocotrienol in the manufacture of a medicine to treat a disease caused by oxidation of LDL, such as atherosclerosis, since HerbiesNaturals discloses a medicament having been manufactured comprising α-tocopherol, γ-tocopherol, and mixed tocotrienols, and Christen et al. discloses that the activity of α-tocopherol as an LDL anti-oxidant requires γ-tocopherol. One would also have been motivated since the metabolites of α-tocopherol, 2,5,7,8-tetramethyl-2(2'-carboxyethyl)-6-hydroxychroman, and γ-tocopherol, 2,7,8-trimethyl-2-(2'-carboxyethyl)-6-hydroxychroman disclosed in Schultz et al. and Darko et al., respectively, are known in the art. Further, it is prima facie obvious to employ a known metabolite in the manufacture of a composition.

Applicant's attention is directed to *In re Pearson*, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974), it was held that; a recitation of intended use in a claim directed to a composition does not impose any limitations which differentiates the claimed composition from those which are known in the art. Similarly, the intended use in a claim directed to a method of manufacturing a composition is not seen to impose any patentable limitations on the method of manufacturing a composition in Claims 4-7.

Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karl Stiller whose telephone number is 703-306-3219. The examiner can normally be reached Monday through Friday, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie can be reached at 703-308-4612. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4556 for regular communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Stiller: ks
November 19, 2001

MINNA MOEZIE, J.D.
SUPERVISORY PATENT EXAMINER
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